



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

201 W. Preston Street • Baltimore, Maryland 21201

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

October 16, 2012

Dear Colleagues,

This report is to provide you updated clinical and diagnostic guidance related to the national outbreak of fungal meningitis and peripheral joint infections related to contaminated injectable steroids. We also want to remind clinicians to report any infections, fungal or otherwise, that may be related to a contaminated product or medication, including any invasive fungal infections related to any NECC product.

To date, Maryland has had 16 cases of fungal meningitis, including 1 death, among the patients who received one of three implicated lots of contaminated methylprednisolone acetate from New England Compounding Center since May 21, 2012. Updated information regarding the situation in Maryland is available: <http://ideha.dhmh.maryland.gov/OIDEOR/SIPOR/SitePages/meningitis.aspx>. Nationally, most reported cases have had meningitis, although a few joint infections have been identified in other states.

Clinical Update:

DHMH would like clinicians to remain aware of updated diagnostic and clinical guidance from CDC, including: <http://www.cdc.gov/hai/outbreaks/clinicians/index.html>.

1. CDC recommendations for antifungal therapy, based upon growing evidence that *Exserohilum rostratum* (brown-black mold) is the predominant pathogen in this outbreak (although a single case of *Aspergillus* and *Cladosporium* species have each been identified) includes:
 - a. Recommendation for monotherapy in certain situations for suspect fungal meningitis with Voriconazole.
 - b. Recommendation for consideration of use of liposomal Amphotericin B.
 - c. Recommendation for use of intravenous and oral Voriconazole.
 - d. Recommendation for monitoring Voriconazole trough levels.
 - e. Drug interactions and toxicity of Voriconazole.
 - f. Duration of antifungal therapy for fungal meningitis/parameningeal infections.
 - g. No antifungal prophylaxis is recommended in this situation.
 - h. *At this time, CDC does **not** recommend empiric antifungal therapy for symptomatic patients who have normal cerebrospinal fluid laboratory examination. These patients should be closely monitored and re-evaluated for progression of symptoms. Should the patient have progression of symptoms, a lumbar puncture should be repeated immediately, using a different site than was used for the epidural injection when possible.*

2. Diagnostic recommendations from CDC for CSF and other specimen testing include: (http://www.cdc.gov/hai/outbreaks/clinicians/instructions_testingandsubmission.html):
- These instructions are meant to supplement routine laboratory and microbiologic tests deemed necessary by the clinical team and should not replace existing diagnostic protocol.
 - CDC is no longer recommending testing serum for Aspergillus antigen (serum galactomannan assay).
 - CDC is no longer recommending testing CSF for mycobacterial culture, unless clinically indicated.
 - Specimen shipping information: contact the State Health Department and State Public Health Laboratory to coordinate shipment of specimens to CDC for further testing.

FDA MedWatch Update

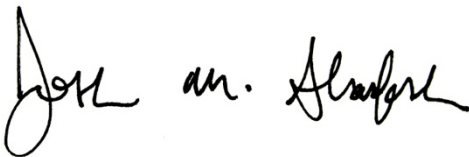
On October 15, 2012, the Food and Drug Administration (FDA) released a MedWatch notice for clinicians who received any NECC products administered since May 21, 2012. At this time, Maryland DHMH is not aware of any cases definitively linked to any other NECC products that are outside the 3 contaminated lots of methylprednisolone acetate. However, specifics related to the MedWatch notification can be addressed by the FDA at the following link: <http://www.fda.gov/Drugs/DrugSafety/ucm322734.htm>.

Updates, FAQs, additional guidance will be available on the FDA website: (<http://www.fda.gov/>). As always, DHMH reminds clinicians to report any infections, fungal or otherwise, that may be related to a contaminated product or medication, including any invasive fungal infections related to any NECC product.

Sincerely,



Lucy Wilson, M.D., Sc.M.
Chief, Center for Surveillance, Infection Prevention and Outbreak Response



Joshua Sharfstein, M.D.
Secretary